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For two-letter codes and other abbreviations, refer to the "Guid-  
ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.

(54) Title: PHARMACEUTICAL COMPOSITIONS OF GANCICLOVIR

(57) Abstract: The technical field of the invention relates to pharmaceutical compositions of 9-(1,3-dihydroxy-2-propoxymethyl) guanine (ganciclovir) that are stable and contain more than 1% water content. One pharmaceutical composition includes ganciclovir having more than about 1% water content, and one or more pharmaceutically acceptable excipients. The ganciclovir retains at least about 97% of its initial purity after one month, at least about 96% of its initial purity after two months, and at least about 95% of its initial purity after three months when stored at 40°C and 75% RH. In particular, the water content may be between about 2% and about 6%.

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## INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61K31/522 A61P31/12 A61P31/22

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61K A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, EMBASE, CHEM ABS Data, PASCAL, SCISEARCH

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 642 346 A (CHAN TAI W ET AL) 10 February 1987 (1987-02-10) cited in the application column 1, line 15,16; examples column 2, line 10-13 ---	1-36
Y	WO 98 10768 A (GLAXO GROUP LTD ;LUDWIG JOHN (US)) 19 March 1998 (1998-03-19) page 1 -page 3; examples ---	1-36
Y	US 4 355 032 A (MARTIN JOHN C ET AL) 19 October 1982 (1982-10-19) cited in the application the whole document ---	1-36
A	EP 1 023 899 A (WAKAMOTO PHARMA CO LTD) 2 August 2000 (2000-08-02) example 34 -----	1-38

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

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- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*&\* document member of the same patent family

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# INTERNATIONAL SEARCH REPORT

PCT/IB 03/04664

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: —  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy Although claims 33-36 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

PCT/IB 03/04664

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 4642346	A	10-02-1987	NONE	
WO 9810768	A	19-03-1998	AU WO	4384297 A 9810768 A1
US 4355032	A	19-10-1982	AT	15899 T
			AU	572086 B2
			AU	8389282 A
			BR	8202931 A
			CA	1305139 C
			CA	1305140 C2
			CA	1305141 C2
			CS	235018 B2
			CS	235042 B2
			CS	235043 B2
			CS	235044 B2
			DD	203052 A5
			DD	213218 A5
			DE	3266644 D1
			DK	227782 A ,B,
			DK	504183 A ,B,
			EP	0066208 A1
			ES	8404355 A1
			ES	8500276 A1
			ES	8507549 A1
			ES	8601204 A1
			ES	8606869 A1
			ES	8701496 A1
			ES	8505681 A1
			FI	73682 B
			GR	76459 A1
			HK	67088 A
			HU	186514 B
			HU	188000 B
			IE	53731 B1
			IL	65836 A
			IN	156469 A1
			IN	160603 A1
			IN	160604 A1
			IN	160605 A1
			JP	1844198 C
			JP	4217983 A
			JP	5029399 B
			JP	1721035 C
			JP	4006195 B
			JP	57203086 A
			KR	8904663 B1
			LU	88334 A9
			MY	79387 A
			NO	821676 A ,B,
			NO	874847 A ,B,
			NO	890476 A ,B,
			NO	890477 A ,B,
			NZ	200691 A
			PH	17975 A
EP 1023899	A	02-08-2000	AU EP	9186398 A 1023899 A1
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# INTERNATIONAL SEARCH REPORT

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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EP 1023899

A

WO

9916447 A1

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